

# Inelastic bandages maintain their hemodynamic effectiveness over time despite significant pressure loss

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**Background:** It is widely believed that the loss of compression pressure of inelastic bandages is associated with a loss of efficacy in contrast to elastic material, which maintains its pressure and performance. This study compared the effect exerted by inelastic bandages vs elastic compression stockings on the venous pumping function in patients with severe superficial venous insufficiency immediately after application and 1 week later.

**Methods:** Ejection fraction (EF) of the calf pump was measured in 18 patients presenting with bilateral reflux in the great saphenous vein (CEAP C<sub>3</sub>-C<sub>5</sub>) without any compression and immediately after application of an inelastic bandage on one leg and an elastic compression stocking on the other leg. Measurements were repeated 1 week later, before compression removal. EF was measured using a plethysmographic technique. The changes of interface pressure of the applied compression products were recorded simultaneously with EF measurements.

**Results:** After application, bandages and stockings achieved a significant improvement of EF ( $P < .001$ ) that was much more pronounced in the bandaged legs. The median resting pressure was 45 mm Hg (interquartile range, 41-48.5 mm Hg) under the stockings and 64.5 mm Hg (interquartile range, 51-80 mm Hg) under the bandages. After 1 week, EF was still significantly improved in the bandaged leg ( $P < .001$ ), but not under the stockings. At this time, the pressure under the stockings was only slightly reduced (5.9% supine, 3.6% standing), but the mean pressure loss under the bandages was much higher (54.3% supine, 35.4% standing).

**Conclusion:** The findings supporting inelastic compression are important in explaining the benefits of its use in chronic venous insufficiency. Inelastic bandages maintain their superior efficacy on the venous pumping function after a wearing time of 1 week, despite a significant loss of pressure. (J Vasc Surg 2010;52:925-31.)

Compression therapy is a very effective treatment modality in several indications. However, some mechanisms of action are only poorly understood. In patients with deep vein thrombosis, the main goal of treatment is the reduction of swelling, pain, and inflammation. The efficiency of the venous calf pump is inadequate in patients with chronic venous insufficiency, which can be characterized by a reduced ejection fraction (EF) of blood pumped up from the lower leg during exercise.<sup>1</sup> Compression therapy is able to improve EF, and inelastic bandages were significantly more effective than elastic material.<sup>2</sup> Inelastic material is blamed for losing its hemodynamic effectiveness very quickly owing to the immediate pressure loss after application, even when applied under full stretch to exert strong or very strong pressure. On the other hand, elastic material is believed to lose much less pressure and therefore to maintain its hemodynamic effect over time.

This study investigated the hemodynamic effectiveness of an elastic stocking kit on one leg compared with an inelastic bandage on the other leg after a wear time of 1 week, correlated with the decline in interface pressure.

## METHODS

This study was approved by the Ethical Committee of our Health District. All participants were informed about the investigation and gave their written informed consent.

**Participants.** The study recruited 18 patients (11 men and 7 women; mean age,  $58.8 \pm 11.2$  years) presenting with symptomatic signs of chronic venous insufficiency (CEAP C<sub>3</sub>-C<sub>5</sub>) and bilateral reflux in the great saphenous vein (GSV; Table).

**Inclusion criteria.** All patients had bilateral primary superficial venous insufficiency of the GSV, including terminal and preterminal valve incompetence, diagnosed by duplex ultrasound (DU) scanner with linear 7.5- to 10-MHz Esaote Technos probe (Esaote s.p.a. Genoa, Italy). The venous diameter in the standing position 2 cm below the junction was  $>1$  cm, and venous reflux time after manual calf compression was  $>3$  seconds. The DU investigation showed that no patients were affected by deep venous insufficiency or obstruction. The criteria to exclude deep venous insufficiency were no reflux in the common femoral, popliteal, and tibial veins examined with the patient standing, during Valsalva maneuver or after manual calf compression. Criteria to exclude venous obstruction were common femoral, popliteal, and tibial veins easily compressible under DU probe compression while standing

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**Table 1.** Clinical profile of the patients and comparison of results in legs receiving elastic kit (EK) and inelastic bandage (IB) compression

Pt	Age	Sex	Leg distribution		CEAP <sup>a</sup>		Vein diameter		Ejection fraction	
		M	EK	IB	EK	IB	EK	IB	EK	IB
1	54	M	Right	Left	3	5	11	13	35.4	41.9
2	62	M	Left	Right	3	3	12	12	31.7	16.7
3	67	M	Left	Right	5	4	13	12	40.4	34.3
4	49	M	Right	Left	4	4	13	14	16.4	19.5
5	71	F	Right	Left	3	3	12	13	34.1	33.0
6	42	M	Right	Left	4	3	14	12	27.1	34.7
7	53	F	Right	Left	3	4	13	14	29.5	33.8
8	65	M	Left	Right	4	3	13	12	23.1	20.7
9	54	M	Left	Right	4	3	11	12	50.1	42.1
10	29	F	Left	Right	3	3	12	11	43.8	37.0
11	76	M	Left	Right	3	3	12	11	24.0	26.6
12	64	M	Left	Right	4	4	12	12	42.0	44.8
13	65	M	Left	Right	3	3	12	11	42.5	16.3
14	66	F	Left	Right	4	5	11	13	37.0	41.5
15	60	F	Right	Left	3	3	12	11	19.1	15.8
16	55	M	Right	Left	5	5	13	13	34.1	32.8
17	69	F	Right	Left	4	4	13	14	18.0	16.0
18	57	F	Right	Left	3	3	12	12	23.7	38.3

F, Female; M, male.

<sup>a</sup>The numbers in the CEAP column correspond to the C class.

and phasic flow signals during respiration by using the Doppler mode while supine.

**Exclusion criteria.** The study excluded patients with a competent terminal or preterminal valve, or both, with venous diameter in the standing position 2 cm below the junction <1 cm, with venous reflux time <3 seconds, with restricted walking mobility, with a body mass index >30 kg/m<sup>2</sup>, or with an ankle-brachial pressure index measured by Doppler of <0.8.

Patients were examined in the midmorning in a quiet room, with a constant temperature of about 22°C in baseline conditions without any compression devices. After the baseline measurements, an elastic compression device was placed on one leg and an inelastic bandage on the other leg. The measurements were repeated immediately after the compression devices were applied, designated time 0 (T0), and before their removal after 7 days (T7).

**Compression devices.** The graduated elastic compression stocking kit (Ulcer Kit Pro; Gloriamed, Menaggio, Italy) consisted of one liner exerting 24 mm Hg topped by one natural rubber, round-knitted elastic stocking exerting an additional 23 to 32 mm Hg. Knee-high stockings were provided in small, medium, and large sizes and were adjusted to the individual leg depending on the ankle circumference. The given pressure ranges are provided by the manufacturer, but the mean actual pressure resulting from the stockings was measured on the individual legs in all patients. The patients were asked to wear the compression device continuously day and night. In case of pain overnight, they could remove the outer stocking and wear only the liner.

The multilayer, multicomponent inelastic bandage consisted of a layer of cotton padding (Cellona), a short, stretch

nonadhesive bandage (Rosidal K), and a cohesive, short stretch bandage on top (Mollelast; Lohmann & Rauscher GmbH & Co KG, Rengsdorf, Germany). The three components were applied in a spiral fashion, with 50% overlap between the layers from the base of the toes up to 1 cm below the strain gauge. Rosidal K and Mollelast were applied under full stretch. The inelastic bandages stayed in place 1 week.\*

Random allocation of stockings and bandages to the right or left leg was performed by using a list randomizer (<http://www.random.org/lists/>).

**Strain gauge plethysmography and baseline measurements.** The EF was measured in both legs by strain gauge plethysmography (SGP) using a method in which the transducer is placed proximally to the compression device,<sup>3</sup> as we have described in previous studies.<sup>2,4</sup> SGP with an Angioflow2 indium-gallium alloy probe (Microlab, Padua, Italy) was used to measure the changes of the leg volume. This method has been proven suitable for recording volume changes of the leg segment to which it is applied.<sup>5,6</sup>

The probe is placed 5 cm distal to the patella with the patient supine. After calibration, the examined leg is elevated above heart level to empty the leg veins and to obtain a minimum blood volume in the leg. After 2 minutes, when a new stable baseline is recorded, the patient stands up with the weight placed on the opposite leg until a stable signal is achieved. The resulting volume increase after refilling of the veins is defined as venous volume (VV). Then the patient is

\*These compression products should be taken as examples for elastic (stockings) and inelastic compression devices (bandages). Similar materials are available throughout the world by subsidiaries of the indicated companies.

asked to perform 20 standardized steps in 20 seconds and to return to the original position. The resulting volume decrease corresponds to the ejected volume (EV). The ejection fraction (EF) is defined by the percent reduction of the local blood volume and calculated according to the formula  $EF = 100 \times EV/VV$ .

**EF and interface pressure measurements after compression.** After this baseline test, the elastic kit was applied on one leg and the inelastic bandage on the other leg according to a randomized sequence and EF measurements were repeated. Simultaneously with the plethysmographic recording, the interface pressure (IP) between the compression devices and the skin was measured by means of a Picopress device with a pressure probe (Microlabitalia, Padua, Italy). The probe, which is 5-cm in diameter and <1 cm thick, is placed at the medial aspect of the leg where the tendinous part of the gastrocnemius muscle turns into its muscular part and is filled with 2 mL of air during measurement.<sup>7</sup> The Picopress and SGP were connected by a data logger to a multichannel recorder for simultaneous and continuous data recording.

The following variables were calculated:

- Ejection fraction ( $EF = 100 \times EV/VV$ ).
- Supine and standing pressure and static stiffness index (SSI), defined as the difference between pressures in the standing and supine positions.<sup>7,8</sup>
- Walking pressure amplitudes (WPA), defined as the difference between systolic and diastolic interface pressure during movement.

**Repetition of measurements.** After this first test, the patients were asked to wear their compression devices for 7 days. The pressure probes of the Picopress monitor were left in place under the compression device, deflated, for 1 week. This was done to guarantee that the interface pressure was assessed exactly at the same site with each measurement. The skin area where the strain gauge probe was placed was carefully marked to replace it in exactly the same position for the second test and to minimize variability.

After 7 days (T7), and before the compression devices were removed, the pressure and strain gauge probes were reconnected to the measuring devices. Both devices were calibrated, and the measurements were repeated using exactly the same protocol as in the T0 test.

**Statistics.** Medians with interquartile ranges (IQR) and maximal and minimal values are given. Comparisons were made between baseline and the outcomes immediately after application of compression (T0) and 7 days later (T7) using the nonparametric Friedman test with Dunn's multiple comparisons. The Wilcoxon test was used for the pairwise comparison of the initial interface pressure with the values after 1 week, and the Mann-Whitney test was used to compare the pressure values of the stockings with those of the bandages. The Spearman rank test was used to quantify correlations. Differences with a value of  $P < .05$  were considered statistically significant. The graphs and the statistical evaluations were generated by using Prism 5 software (GraphPad, San Diego, Calif).

## RESULTS

All the patients were able to adhere to the protocol (compliance 100%). None removed the outer natural rubber stocking, although three patients complained of some discomfort overnight. No complaints were reported about the inelastic bandage.

**Baseline measurements.** After randomization, the compression devices were evenly distributed between the two legs. The legs that underwent elastic and inelastic compression did not differ significantly in CEAP classification or GSV diameter. The pumping function at baseline was significantly reduced in both legs compared with healthy legs. EF, which has a normal value >60%,<sup>2</sup> was 32.9% (IQR, 23.55%-40.8%) in the stocking group and 33.4% (IQR 18.8-39.1) in the inelastic bandage group, without statistical difference (Table).

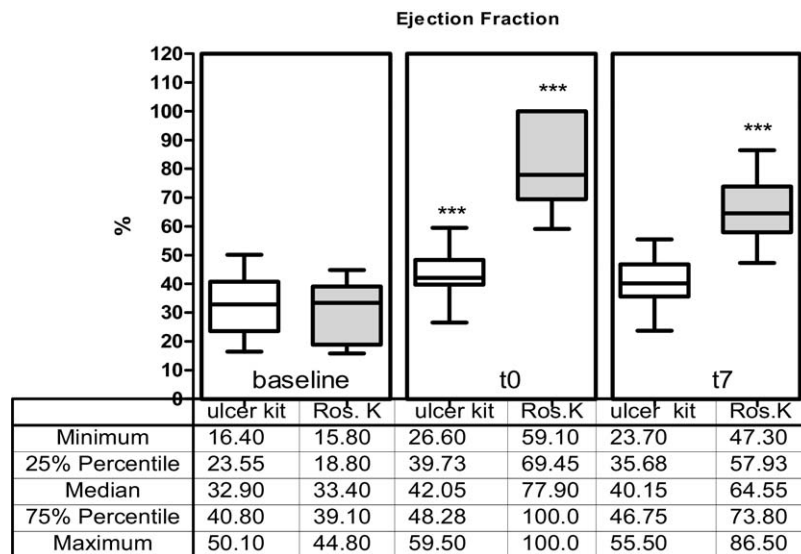
**Influence of compression devices after application (T0).** The elastic material induced an improvement of EF to 42.05% (IQR, 39.73%-48.28%;  $P < .001$ ), but the inelastic bandages led to a much higher increase to 77.9% (IQR 69.45%-100%;  $P < .001$ ), restoring EF into the normal range (Fig 1).

In the supine position, the median interface pressure of the stockings was 45 mm Hg (IQR, 41-48.5 mm Hg) and was 64.5 mm Hg (IQR, 61.5-80 mm Hg;  $P < .001$ ) for the bandages (Fig 2). By standing up, the pressure increased by about 4 mm Hg with elastic stockings and by about 30 mm Hg with inelastic material ( $P < .001$ ). The pressure difference, the SSI,<sup>8,9</sup> was 4 mm Hg (IQR, 3-6 mm Hg) and 29 mm Hg (IQR, 20.75-38 mm Hg), respectively. The WPA during exercise was 4 mm Hg (IQR, 2.75-5 mm Hg) with elastic stockings and 34.5 mm Hg (IQR 28.75-39.5 mm Hg) with inelastic bandages ( $P < .001$ ).

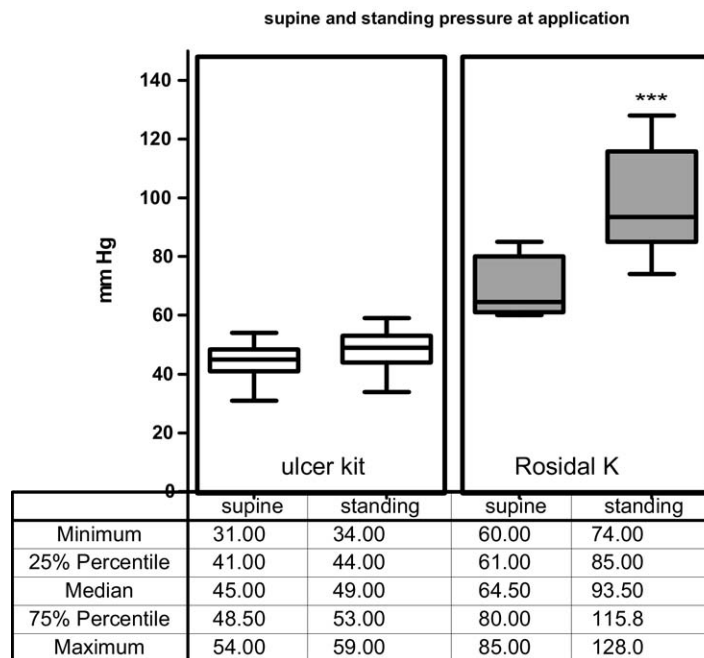
**Influence of compression devices after 1 week (T7).** After 1 week, the interface pressure under the inelastic bandage showed a significant drop to 30.5 mm Hg (IQR, 28-32.25 mm Hg) in the supine position and to 61 mm Hg (IQR, 58.75-63.75 mm Hg) while standing ( $P < .001$ ), whereas the pressure with elastic stocking remained nearly unchanged. At this point, the supine pressure was higher with elastic stockings than with inelastic material, whereas the pressure while standing stayed significantly higher with the inelastic bandage (Fig 3). SSI and WPA were still significantly higher ( $P < .001$  for both parameters) under inelastic than elastic material: 31 mm Hg (IQR, 25.75-35 mm Hg) vs 4.5 mm Hg (IQR, 3.75-7 mm Hg) for SSI and 27 mm Hg (IQR 20.25-31) vs 4 mm Hg (IQR 3-5) for WPA.

Despite the significant pressure drop with inelastic bandages (-54% in the supine and -35% in the standing position), EF was still significantly higher than at baseline, reaching median values in the normal range ( $P < .001$ ). For elastic kits, compared with baseline, only a statistically nonsignificant improvement was recorded (Fig 4).

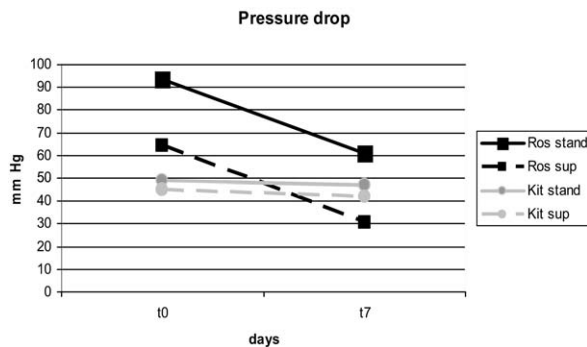
**Correlation between EF and bandage pressure.** The results from measurements at T0 and T7 showed a



**Fig 1.** Box and whisker plots show the ejection fraction before (*baseline*), immediately after compression (*t0*), and 7 days later (*t7*) in 18 patients. The *horizontal line* in the middle of each box indicates the median; the *top* and *bottom borders* of the box mark the 75th and 25th percentiles, respectively, and the *whiskers* mark the 90th and 10th percentiles. *Gray*, inelastic bandages; *white*, elastic stockings. \*\*\* $P < .001$  compared with baseline (Friedman test).



**Fig 2.** Box and whisker plots show the interface pressure in supine and standing position immediately after compression device application in 18 patients. The *horizontal line* in the middle of each box indicates the median; the *top* and *bottom borders* of the box mark the 75th and 25th percentiles, respectively, and the *whiskers* mark the 90th and 10th percentiles. *Gray*, inelastic bandages; *white*, elastic stockings. *Gray*, inelastic bandages (Rosidal); *white*, elastic stockings. \*\*\* $P < .001$  compared with supine pressure (Friedman test).



**Fig 3.** Median values of interface pressure exerted by inelastic bandages (Ros, *black*) compared with elastic stockings (Kit, *grey*) after application ( $t_0$ ) and 7 days later ( $t_7$ ) in the supine and standing positions in 18 patients. The pressure loss after 7 days is significant for stockings and bandages in supine and in standing positions ( $P < .001$ ; Wilcoxon test).

statistically highly significant correlation between EF and the sub-bandage pressure peaks ( $P < .001$ , Pearson  $r = 0.644$ ), the SSI (Pearson  $r = 0.576$ ), and WPA (not shown; Pearson  $r = -0.5766$ ; Fig 5).

## DISCUSSION

The method we have used to evaluate venous pumping function was originally introduced by a group of clinical physiologists who measured the EF of the venous calf pump proximal to a plaster on the lower leg in healthy volunteers.<sup>3</sup> By putting water filled pads under the plaster, they were able to demonstrate an increase of EF by counteracting stasis in the immobilized lower leg. We have shown that this procedure is able to discriminate healthy individuals from patients with venous insufficiency. In healthy volunteers with normal calf pump function, the values of EF are  $>60\%$ , whereas in patients affected by venous insufficiency, the pumping function is compromised as reflected by a significant reduction of EF.<sup>2</sup>

This method can also be used to quantify the hemodynamic improvement produced by different compression devices in healthy individuals as well as in patients with venous insufficiency.<sup>2,3</sup> The variability of the method, showing a variation coefficient of 7.5%, has already been reported.<sup>2</sup> EF can also be measured by placing the detecting device over the bandage (air plethysmography), but this method seems to be less reliable in discriminating between healthy individuals and patients with vein disease and between different degrees of venous insufficiency.<sup>10-15</sup> This could be because measurement of these parameters is influenced by the reduction of the basic volume under compression taking place in the region of the calf pump. With the method we used, the measuring probe is placed proximally to the bandage, directly on the skin; therefore, the measured volume changes reflect changes of the leg and not of the bandage.

Our results show that the elastic ulcer kit, exerting a supine pressure of about 45 mm Hg, improves the calf pumping function significantly. However, the slight im-

provement is far from restoring a normal pumping function. After application of inelastic bandages, improvement of the calf pumping function was significantly more pronounced, restoring EF into the normal range. This finding is consistent with our previous observations.<sup>2,4</sup>

Other investigators using air plethysmography,<sup>16,17</sup> foot volumetry,<sup>18-20</sup> or SGP<sup>21</sup> have also demonstrated an improvement of venous pumping function by medical compression stockings. Only a few studies, however, have compared the effects of elastic stockings and inelastic bandages. In patients with severe stages of chronic venous insufficiency ( $C_6$ ) and with involvement of deep veins due to post-thrombotic syndrome, air plethysmography showed that inelastic bandages were significantly more effective in reducing venous reflux than elastic bandages applied with the same pressure.<sup>22</sup>

No studies to date, to our knowledge, have reported the long-term efficacy of compression devices worn for several days. The definitive evidence to prove the effects of compression over time can be provided only by measuring EF after application of a compression device and 1 week later.

Inelastic compression loses pressure over time, even when applied under full stretch to exert high pressure at application; this pressure loss starts immediately after application and tends to stabilize after 1 day. The pressure drop is basically because of edema reduction and fluid shift from the lower leg. Because the superior hemodynamic effects of inelastic compression are obviously associated with its high pressure, it is assumed that its effectiveness will decrease after a few days owing to pressure loss. This assumption contrasts with findings from a previous study in which we demonstrated that inelastic material is effective even at a low pressure of 20 mm Hg, improving EF significantly although unable to restore a normal value that is possible only with higher pressure.<sup>4</sup>

In our study we observed a significant pressure drop after 1 week, more in the supine than in the standing position. Aligned with this dramatic pressure loss was a significant decrease of EF, which, however, stayed in the normal range. This clearly shows that despite a significant pressure drop, an inelastic bandage is able to maintain its positive effects on the venous hemodynamic impairment for 7 days.

The elastic kit tends to maintain its pressure over time, showing only a very small and nonsignificant pressure loss after 1 week, both in the supine and standing positions. This is associated with a minor reduction of EF, which after 1 week does not show a significant difference compared with the baseline value without compression. Our experiments show once again that the static interface pressure is not the only important determinant for improving venous pump function, but that the elastic property of the compression material is also very important.

Inelastic bandages maintain their structural property even after several days. They do not give way to the muscle volume increase during muscle contraction, thereby producing much higher standing pressure and pressure peaks during walking compared with the supine resting pressure. Even after a wear time of 7 days, the standing pressure and



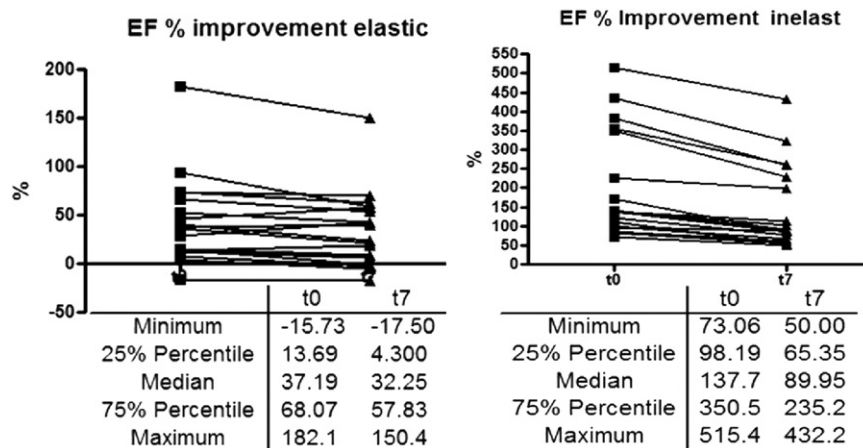


Fig 4. The percentage improvement of ejection fraction (EF) under compression was much higher ( $P < .001$ ) under inelastic material, initially and after 1 week in 18 patients. It decreased after 7 days for both materials in all patients.

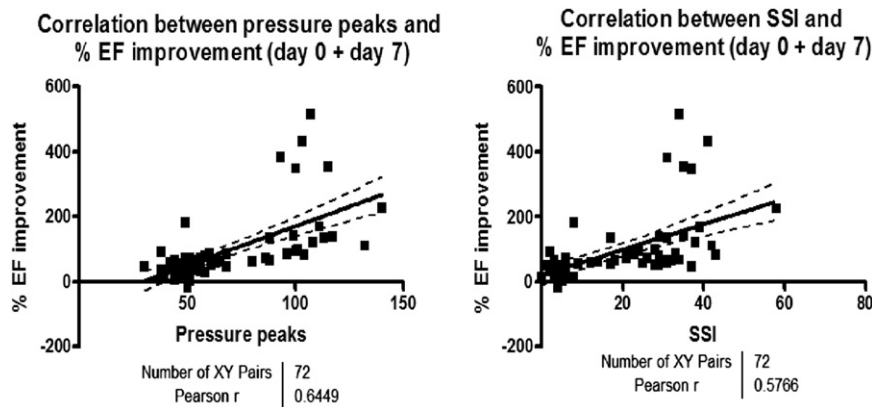


Fig 5. Positive correlation was found between ejection fraction (EF) (Left) improvement and pressure peaks and (Right) static stiffness index (SSI) at application (day 0) and after 7 days.

the pressure peaks during walking, although significantly reduced compared with application ( $P < .001$ ),<sup>23</sup> remain in the strong to very strong pressure range.<sup>24</sup> Also SSI and WPA (another stiffness indicator) remain very high and substantially unchanged compared with the values recorded at application. These high WPA produced by the inelastic bandage act in a similar way to an intermittent pneumatic pressure pump, exerting a “massaging effect” on the leg that seems to be a major factor in the improvement of calf pump function. As already reported<sup>2</sup> and also in this series of patients, we observed a positive correlation not only between EF and standing pressure but also between EF and SSI and WPA.

Such high pressure differences between resting and standing and between muscle diastole and systole cannot be achieved with elastic material, even when applied with a strong pressure of 45 mm Hg. Elastic material gives way when the calf muscle contracts, exerting standing pressure and pressure peaks during walking that are only slightly higher than the resting pressure. A sustained pressure, characteristic of elastic

material, is not able to act like an intermittent pump and to improve EF significantly, both at application (independently by exerted pressure)<sup>4</sup> and over time.

Stockings and bandages were both well tolerated and worn for 1 week by all participants. The clinical implications of our result are very important. Because the inelastic bandage is blamed for losing its therapeutic effect over time, this would mean that it is useless and may be even harmful to use it for several days, as often happens when treating patients with deep vein thrombosis or leg ulcer. Our data show that this is not the case; on the contrary, inelastic compression devices are not only more comfortable but are even more effective than elastic, both at application and at least up to 1 week. This is reassuring in the treatment of those patients when some days or 1 week wearing time is advisable.

Even concerning the cost of the compression material, although the stocking kits are more expensive than the bandage material, the stocking can be used up to 6 months; however, the bandage is changed every week. The com-

pression component of the bandage material used for this test and in our daily practice can be washed and reused, and only the padding layers are disposable, so that the material costs for the bandage are approximately the same as for the stocking for a treatment period of 24 weeks. If disposable bandage material were used in weekly intervals, the bandage cost would be much higher.

A weakness of our study may be the potential bias introduced by the fact that both legs of our patients, presenting different severity of venous incompetence, were treated, one by the stocking kit and the other by inelastic bandages. This experimental setup was chosen because we were interested in quantifying the change of venous pumping performance after 1 week, which may vary between different individuals due to different degrees of mobility and physical activities. Therefore, the potential criticism that the degree of venous insufficiency may not have been equivalent between the legs would still be a problem if only one leg of different probands had been examined. In fact, the baseline values of EF between the two legs in our study were similar. In a different study design (eg, crossover), not only the clinical but also the environmental conditions of the patients would have varied from time to time.

Future studies of the efficacy of different compression devices would be of interest in other subgroups of patients with proximal venous obstructions, deep vein thrombosis, post-thrombotic syndrome, and mixed, arteriovenous disease.

## CONCLUSIONS

In patients with severe superficial venous incompetence, inelastic material is able to restore the venous pumping function to within the normal range and maintain its effect over 1 week, despite a significant pressure loss. Elastic material slightly improves the venous pumping function at application and 1 week later, but is unable to normalize the venous pump.

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## AUTHOR CONTRIBUTIONS

Conception and design: GM, HP  
Analysis and interpretation: GM, HP  
Data collection: GM  
Writing the article: GM, HP  
Critical revision of the article: GM, HP  
Final approval of the article: GM, HP  
Statistical analysis: HP  
Obtained funding: Not applicable  
Overall responsibility: GM

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